

## **REMARKS**

Reconsideration and allowance are requested in view of the amendments and remarks herein.

### **The Examination**

In the Office Action mailed August 28, 2006, claims 1, 4, 5, 7-11, 14, 18, 20, and 23-26 were rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. We have amended independent claims 1, 23, and 24 and dependent claims 7 and 9 to overcome the Examiner's rejections. We have also added independent claim 27 to further clarify our invention.

Claim 22 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent 5,309,916 to Hatscheck et al. ("Hatscheck") in view of U.S. Patent 5,316,008 to Suga et al. ("Suga"). We have deleted claim 22.

U.S. Patent 6,676,608 to Keren was cited as being pertinent to the Applicant's disclosure.

### **Amended and New Claims**

In order to more clearly describe the invention, we have amended independent claims 1, 23, and 24, and added independent claim 27. We have further amended dependent claims 4, 7, and 9 to comply with the independent claims. With these amendments claims 1, 4, 5, 7-10, 14, 18-20, and 23-27 are pending in this Application. New claim 27 has similar limitations to amended claim 1, but further clarifies the first and second time-dependent properties that are critical to our invention.

As amended, independent claims 1, 23, and 24 describe a hand-held device for measuring blood pressure that features first and second optical modules, both operating in reflection mode, and an electrode pair. When the hand-held component is held next to the patient's skin, the optical sensors measure first and second signals in a reflection-mode geometry, while the electrodes measure a third signal. A processing module, comprised by the hand-held component, receives the first, second, and third signals and calculates: 1) a first time-dependent property from the first and second signals; and 2) a second time-dependent property from the third signal and either (or both) of the first and

second signals. The first time-dependent property relates to a time-dependent variation in arterial properties, while the second time-dependent property relates to a change in blood pressure. The processing module then compares the first and second time-dependent properties to a mathematical model to calculate a blood pressure value.

Support for amendments concerning a processor that measures first and second time-dependent properties from the first, second, and third signals is found throughout our specification, particularly in Paragraphs [60] - [64] and Figs. 2A, 2B, 3 and 11. For example, in paragraph [60] the specification describes an electrode pair that measures an electrical signal to generate a third set of information:

[60] In one embodiment, the mechanical module (27) of the device of Fig. 1 is replaced with an electrical impedance (EI) sensor that features an electrode pair that measures the change of electrical impedance of the underlying arterial segment (emphasis added)

Paragraph [60] goes on to describe how a signal measured from the electrode pair (i.e. an ‘impedance waveform’), when processed in combination with a signal from one of the optical sensors, yields a time-dependent property. This parameter, referred to in our independent claims as the ‘second time-dependent property’, is the ‘separation between pulses in the impedance waveform and those in the optical waveform’. When processed with our algorithm, this property gives a difference in blood pressure:

[60] When the EI sensor replaces the thin-film pressure sensor, the separation between pulses in the impedance waveform and those in the optical waveform yield a difference in pressure ( $\Delta P$ ) between the systolic and diastolic pressure. Combined with the below-described calibration process, the magnitude of each pulse can be correlated to the systolic pressure. The entire impedance waveform can therefore be used in place of the pressure waveform to determine systolic and diastolic pressure. (emphasis added)

Paragraphs [61] - [64] describe how the signals measured from the first and second optical modules yield another time-dependent property (i.e. a ‘time-dependent variation in arterial diameter’). This is referred to in our independent claims as the ‘first time-dependent property’. Paragraph [61] goes on to describe how the first and second time dependent properties ‘can be processed with a mathematical algorithm to determine blood pressure’:

**[61]** In addition to this sensor, the blood pressure-measuring device can include a pair of optical modules, similar to those described in Fig. 1, that measure the time-dependent variation in arterial diameter caused by blood flow. These data, along with data generated by the EI sensor, can be processed with a mathematical algorithm to determine blood pressure. (emphasis added)

Paragraphs [62] and [63] then list an equation (Equation 1) describing the mathematical algorithm. Finally, Paragraph [64] summarizes this process by describing how Equation 1 can be solved to generate a mathematical expression that, using inputs from the optical and electrical sensors, yields a patient's time-dependent, beat-by-beat blood pressure (e.g., P(t)):

**[62]** The mathematical algorithm used for this calculation can take many forms. For example, the paper entitled 'Cuff-less, Continuous Monitoring of Beat-to-Beat Pressure Using Sensor Fusion' (Boo-Ho Yang, et al., submitted to the IEEE Transactions on Biomedical Engineering, 2000) describes an algorithm based on a two-dimensional Navier-Stokes differential equation that models pulsatile flow of a Newtonian liquid (e.g., blood) through an elastic, deformable cylindrical vessel (e.g., an artery). This differential equation can be solved in a number of different ways, and is shown below in Equation 1:

$$\begin{aligned} \frac{\partial u}{\partial t} + u \frac{\partial u}{\partial r} + v \frac{\partial u}{\partial z} &= -\frac{1}{\rho} \frac{\partial P}{\partial z} + \nu \left( \frac{\partial^2 u}{\partial r^2} + \frac{1}{r} \frac{\partial u}{\partial r} + \frac{\partial^2 u}{\partial z^2} \right) \\ \frac{\partial w}{\partial t} + u \frac{\partial w}{\partial r} + v \frac{\partial w}{\partial z} &= -\frac{1}{\rho} \frac{\partial P}{\partial r} + \nu \left( \frac{\partial^2 w}{\partial r^2} + \frac{1}{r} \frac{\partial w}{\partial r} + \frac{\partial^2 w}{\partial z^2} - \frac{w}{r^2} \right) \\ \frac{1}{r} \frac{\partial}{\partial r} (rw) + \frac{\partial u}{\partial z} &= 0 \end{aligned} \quad (1)$$

**[63]** In Equation 1, r,  $\theta$ , z are the cylindrical coordinates of an arterial segment. P denotes pressure,  $\rho$  density,  $\nu$  kinematic viscosity, and  $u(r,z,t)$  and  $w(r,z,t)$  denote the components of velocity in the axial (z) and radial (r) dimensions, respectively.

**[64]** Equation 1 can be solved to generate a mathematical expression that, using inputs from the first and second optical modules and the EI sensor, yields a patient's time-dependent, beat-by-beat blood pressure (e.g., P(t)). (emphasis added)

A phone interview concerning our Application was held on October 3, 2006 with Examiner Mallari; Applicant Banet is very grateful for her time and consideration. During the interview, Applicant Banet described to Examiner Mallari the above-

mentioned amendments and how our specification supports them. Also discussed was a device embodying the invention, and how our resultant invention is removed from the prior art. Examiner Mallari indicated that our amendments would overcome her rejection under 35 U.S.C. Section 112, 1<sup>st</sup> paragraph (note: this opinion was described in a written Interview Summary mailed to Applicants shortly after the interview), but also indicated the proposed amendments would require another search.

### **The Prior Art**

The Examiner cited the following prior art references in the Office Action mailed August 28, 2006.

Hatschek, U.S. Patent 5,309,916 ('Hatschek'), describes a calibrated, cuff-based device that uses two optical sensors and a mathematical model to calculate blood flow properties and from these a blood pressure value.

Suga et al., U.S. Patent 5,316,008 ('Suga'), describes a wrist watch that features a single optical sensor and a pair of electrical sensors for measuring signals from a patient. During operation, the patient wears the wrist watch on one wrist, and places fingers from an opposing hand on the optical and electrical sensors. The wrist watch measures a pulse transit time from the signals and then uses it to calculate a blood pressure.

Keren, U.S. Patent 6,676,608 ('Keren'), describes a method for detecting a 'blood front wave' and ECG using two pulse oximeters on the fingertips and electrodes placed on the arms and chest.

### **Patentability Over The Prior Art**

The Examiner's references, Hatschek and Suga, were applied to claim 22, which we have cancelled.

Keren, a reference made of record, teaches a device that attaches to a patient and receives signals from two conventional pulse oximeters and an ECG to determine a 'blood front wave'. A processor then analyzes the blood front wave to determine a patient's cardiovascular condition, particularly their degree of arteriosclerosis. At a high level, Keren fails to describe even the basic premise of our invention: a method for determining blood pressure using first and second time-dependent properties. At a more detailed level, Keren is also silent to a hand-held component that includes two optical

sensors and an electrical sensor; optical modules operating in reflection mode; and a device that makes measurements when held proximal to a patient's skin.

In summary, we believe our independent claims are adequately supported by our disclosure, as required under 35 U.S.C. Section 112, first paragraph, and are not taught or suggested by the prior art. We therefore ask that the Examiner allow these claims. The dependent claims are even further removed from the prior art and are also supported by our disclosure, and thus we ask that they be allowed as well, and that the Examiner issue a Notice of Allowance for the present Application.

Respectfully submitted,

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